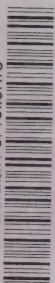


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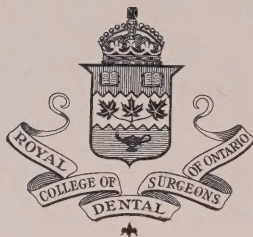
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BILATERALITY OF
DENTAL CARIES ON PREMOLAR AND
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A FOUR YEAR STUDY

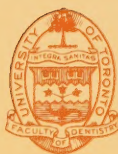
by

D. W. Lewis, S. Shaughnessy,
and T. P. Howley

December, 1980

RESEARCH REPORT

*issued by the
Dental Health Care
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DENTAL CARIES ON PREMOLAR AND
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A FOUR YEAR STUDY

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and T. P. Howley

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Research Report No. 36

Research supported in full through
Demonstration Model Grant DM 381 of
The Ontario Ministry of Health

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ACKNOWLEDGEMENTS

The authors are indebted to the following people.

Dr. J. A. Hargreaves of the University of Alberta who kindly provided the clinical trial data on which the analysis is based. Dr. D. W. Banting of the University of Western Ontario who, some years ago, made the initial inquiry about the epidemiologic evidence for dental caries bilaterality. And Dr. J. V. Marko, a former summer student of the senior author, who originally worked on the caries data. The help of all these persons is gratefully acknowledged.

We also offer our thanks to Betty Conroy who typed this report.



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TABLE OF CONTENTS

ACKNOWLEDGEMENTS

ABSTRACT

LIST OF FIGURES AND TABLES

INTRODUCTION	1
MATERIALS AND METHODS	2
FINDINGS	12
DISCUSSION	20
REFERENCES	25
APPENDIX 1	26

ABSTRACT

Bilaterality of dental caries, the contiguous incidence of caries on corresponding tooth surfaces on the right and left sides of the mouth, has been implicitly assumed in the split-mouth experimental design so often used in fissure sealant and flossing studies. It is surprising that the time of onset of caries on contralateral surfaces has not been studied extensively. A review of the literature revealed only studies using data on caries prevalence (the existence of caries at a single point in time); none used data on caries incidence (the occurrence of caries between two points in time).

Two aspects of bilaterality can be measured: a measure of symmetry tests whether the caries rates (over the whole sample) on each surface of the right-left surface pair are equal; a measure of association tests whether the occurrence of caries on a surface is associated with the occurrence of caries on the corresponding contralateral surface. (This distinction is made clear by the examples in the Appendix.)

This study assesses the bilaterality (symmetry and association) of dental caries incidence using data from a four-year clinical trial of topical fluoride treatment. The caries incidence on the premolar and second molar teeth of 98 control children and 82 treatment children, initially of age 11, was studied. Except for surfaces with very low caries rates, each left-right surface pair for each tooth in each jaw was analyzed.

It was interesting to find that, overall, only about half (42 to 52%) of both smooth and fissure surface pairs were diagnosed as carious on both sides in the same year, with about 30% displaying a one-year lag in bilaterality, and about 20% a two-year lag. Significance tests for symmetry of right-left surface caries attack for each surface pair generally showed no asymmetry. However, nearly half of the 104 incremental surface pair tables analyzed did not show significant association.

The implications of these findings in particular and of symmetry and association in general, to the bilaterality of dental caries incidence are discussed.

iv
LIST OF FIGURES AND TABLES

	<u>Page</u>
FIGURE 1 - Examples of Coding Corrections	5
FIGURE 2 - Scheme for Basic Caries Incidence Matrix	6
TABLE 1 - Basic Caries Incidence Matrix for the Occlusal Surface of the Maxillary Second Molar, Non-Fluoride Group	7
TABLE 2 - Number of Surface Pairs Showing Various Time Spans Between Left-Right Caries Onset, Non-Fluoride Group	7
TABLE 3 - Cross-Sectional Caries Prevalence of the Occlusal Surface of the Maxillary Second Molar, Non-Fluoride Group at Exams 1, 2, 3, 4, and 5	8
TABLE 4 - Caries Increments of the Occlusal Surface of the Maxillary Second Molar, Non-Fluoride Group 1, 2, 3, and 4 years After Sound-Sound Baseline	8
FIGURE 3 - Dental Caries Right-Left Pair Notation and Possible Shifts to Caries State	9
FIGURE 4 - Tests of Symmetry	11
TABLE 5 - Sample of a Basic Caries Incidence Matrix for a Surface with a Low Level of Caries Incidence: Mesial Surface of the Mandibular First Bicuspid, Non-Fluoride Group	13
TABLE 6 - Tests of Association for Cross-Sectional Surface-Pair Tables (Fisher's Exact Test)	15
TABLE 7 - Number and Percent of Tables Displaying Lack of Association at the 5% Significance Level by Surface, by Exam, by Arch, and by Group--Cross Sectional Data	16
TABLE 8 - Tests of Association for Incremental Surface-Pair Tables (Fisher's Exact Test)	17
TABLE 9 - Number and Percent of Tables Displaying Lack of Association at the 5% Significance Level by Surface, by Exam, by Arch, and by Group--Incremental Data	18

BILATERALITY OF DENTAL CARIES ON PREMOLAR AND
SECOND MOLAR TEETH -- A FOUR YEAR STUDY

Introduction

Bilaterality is a long-accepted phenomenon in dental caries epidemiology. In view of this history it is curious to find in the literature that caries bilaterality has not been studied in the expected detail and, indeed, a number of the early studies were incorrectly analyzed. Lu¹ defined bilaterality of dental caries as "the occurrence of caries on similar surfaces of corresponding teeth". He pointed out in 1965 that the concept of bilaterality really includes two notions - that of symmetry of caries attack, and that of association of caries attack. Symmetry concerns the closeness of the overall proportion of caries on a given tooth surface on one side with the overall proportion of caries on the corresponding surface on the other side, for a particular sample of subjects. Association is a measure of the extent to which the caries rate of a given tooth surface on one side of the mouth is dependent upon the caries rate of the corresponding surface on the other side. There is said to be association if the number of subjects with both sides carious or both sides non-carious is greater than the number which would be expected by chance alone.* (Examples of tables showing presence and absence of symmetry and association are presented in Appendix 1.) Symmetry and association may both be present (see Appendix 1, Table E), both be absent (see Appendix 1, Table A), or one may occur in the absence of the other (see Appendix 1, Tables B and D). Lu then proceeded to reanalyze correctly the published cross-sectional bilaterality prevalence data of several previous investigators.

Our interest in bilaterality arose primarily from a concern about the validity of the implicit assumption of dental caries bilaterality in the standard split-mouth clinical trial analyses used in fissure sealant^{2,3,4,5} and flossing⁶ studies. Bilaterality in these types of studies is concerned with dental caries incidence, not prevalence. (Incidence refers to the occurrence of new dental caries on tooth surfaces between two points in time; prevalence refers to the number of surfaces which exhibit caries at a particular point in time.) The preventive agent or procedure applied to the randomly selected side of sound-sound (both sides non-carious) surface pairs is anticipated to reduce or prevent future increments of new decay when compared with the caries incidence on the contralateral (control) surface.

* Statistical association can also occur with a preponderance of unilateral caries; this, however, does not occur in practice. This is referred to as negative association in the Tables C and F in Appendix 1.

This analytical model is based on the assumption that the treated side, if left untreated, would have caries incidence similar to the untreated side. If dental caries incidence, especially over a short one- or two-year period does not exhibit bilaterality, then the split-mouth design is inappropriate. Examination of this literature failed to reveal any investigations of the bilaterality of caries incidence. Previous studies and their reanalyses by Lu¹, are, as mentioned above, based on cross-sectional prevalence data, not on incidence data.

We had on hand the data from a previous longitudinal split-mouth study (Lewis and Hargreaves⁷). This allowed us the opportunity of assessing the validity of bilaterality assumptions. The data and their reanalysis are discussed in the next section.

Materials and Methods

The Lewis and Hargreaves study was a four-year longitudinal design with two independent samples; a treatment (topical fluoride) group and a control (non-fluoride) group. At the beginning of the study 11-year-old children were given clinical and radiographic examinations. These examinations were repeated at yearly intervals for the next four years. Each of the five surfaces (occlusal, mesial, distal, buccal, lingual) of each first and second pre-molar and second molar in the upper and lower jaws on both sides was assessed for the presence and the degree of decay, and coded according to the following scheme:

- 0 - sound;
- 1 - caries into enamel only;
- 2 - caries into dentin, but not into pulp;
- 3 - caries into pulp;
- 5 - restored;
- 6 - extracted;
- 9 - unerupted.

For the purposes of the present study, only those children with five complete yearly records were included. This resulted in an available sample size of 98 (50 males and 48 females) in the non-fluoride group, and 82 (41 males

and 41 females) in the fluoride group. (Although sex differences in bilaterality were not assessed, sexes were combined throughout the study, in order to maintain large enough sample sizes for a suitable analysis. It is assumed that any sex differences are not substantial.)

Two problems with the coding and scoring had to be dealt with before the data could be tabulated and analyzed. The first problem was inconsistent year-to-year scores. Several decision rules were adopted in order to determine these scores reasonably or to eliminate them from the analyses:

- 1) If a score of 1 for a particular tooth surface for one exam was followed by a score of 0 (sound) on the next year's exam, the score of 1 was considered erroneous and was recoded to 0. (The reasonableness of this decision rule has been demonstrated by Kawall, Lewis and Hargreaves in the unpublished examiner error analysis of another clinical trial using the same dental caries scoring scheme.)
- 2) If a score of 2, 3, or 5 for a particular tooth surface was followed by a score of 0 on a later exam, the progression was judged illogical and the scores for all the yearly examinations for that tooth surface were considered missing scores.
- 3) If a particular tooth was reported as being extracted on one exam and some or all of the surfaces were recorded as sound, carious, or restored on any succeeding exam, the scores for all surfaces of the tooth on all five exams were considered missing scores.

The second problem arose where teeth were unerupted or extracted. The following decision rules were used.

- 4) Scores for all five surfaces of a tooth which was unerupted at the time of the fifth examination were considered missing scores for all five examinations.
- 5) All five surfaces of a tooth which erupted between the first and fifth examinations were scored as sound during the examinations when it was as yet unerupted.
- 6) If a tooth was extracted and one or more of the surfaces were recorded as sound on the previous examination, then the score(s) for the previously sound surface(s) was/were recoded to (a) missing score(s) for all five examinations.

Several examples of these decision rules should help make them clearer. These are shown in Figure 1.

The unit of analysis throughout this study is the tooth surface pair; that is, a particular tooth surface on one side of the mouth and the corresponding surface on the other side. Only those pairs in which both the right and left surfaces have non-missing scores are included in the analyses. For each tooth surface, the year of caries incidence (onset) for the left surface is cross-tabulated with the year of caries incidence for the right surface, to form caries incidence matrix as shown diagrammatically in Figure 2 and for actual tooth surface data in Table 1. These cross-tabulations were done separately for the fluoride and non-fluoride samples. From each of these longitudinal incidence tables, five cross-sectional tables (one for each examination time) were derived -- the set of five cross-sectional tables corresponding to the caries incidence table in Table 1 is shown in Table 3. (Note that each table in Table 3 is a prevalence table, showing the distribution of sound and carious surfaces at a particular point in time, whereas Table 1 is an incidence table, showing the approximate time of onset of the caries.)

Given a set of prevalence tables as in Table 3, it is possible to examine caries incidence by deriving tables which summarize the shift in status of sound-sound surface pairs identified at the initial baseline examination (exam 1), up until the end of the first year (exam 2), and from the initial year until the end of the second year (exam 3), and from the initial year until the end of the third year (exam 4), and from the initial year until the end of the fourth year (exam 5). An example of the set of four incremental tables, derived from Table 3, is shown in Table 4.

Figure 3 shows both the labelling of table cells (a, b, c, d) used later and, of more relevance now, the possible shifts in caries status from the sound-sound baseline. In a given time period, both surfaces on the left and right sides may shift from sound to carious or just one of the surfaces may shift from sound to carious. These shifts are indicated by the solid arrows. In a later examination, the unilateral caries state might shift to the bilateral caries state; this is indicated by the dashed arrows. For example, in Table 3, 69 sound-sound pairs are observed in the first examination; in the second examination there are only 45 sound-sound pairs. The first table in Table 4 shows what became of the remaining 24 pairs: 13 of these pairs shifted from sound-sound to carious-carious; 5 pairs shifted from sound-sound to carious on the left side only; and

FIGURE 1

EXAMPLES OF CODING CORRECTIONS

Scoring Scheme:

- 0 - sound
- 1 - caries in enamel
- 2 - caries in dentin
- 3 - caries in pulp
- 5 - restored
- 6 - extracted
- 9 - unerupted
- M - missing score

Rule	Surface	Original Coding					Corrected Coding				
		Exam					Exam				
		1	2	3	4	5	1	2	3	4	5
1.)	Any	0	1	0	1	2	0	0	0	1	2
	Any	0	0	1	1	2	0	0	1	1	2
2.)	Any	0	0	2	0	0	M	M	M	M	M
3.)	Occlusal	0	2	6	6	5	M	M	M	M	M
	Mesial	0	0	6	6	6	M	M	M	M	M
	Distal	0	0	6	6	6	M	M	M	M	M
	Buccal	0	0	6	6	6	M	M	M	M	M
	Lingual	0	0	6	6	6	M	M	M	M	M
4.)	Occlusal	9	9	9	9	9	M	M	M	M	M
	Mesial	9	9	9	9	9	M	M	M	M	M
	Distal	9	9	9	9	9	M	M	M	M	M
	Buccal	9	9	9	9	9	M	M	M	M	M
	Lingual	9	9	9	9	9	M	M	M	M	M
5.)	Occlusal	9	9	0	0	1	0	0	0	0	1
	Mesial	9	9	0	0	0	0	0	0	0	0
	Distal	9	9	0	0	0	0	0	0	0	0
	Buccal	9	9	0	0	0	0	0	0	0	0
	Lingual	9	9	0	0	0	0	0	0	0	0
6.)	Occlusal	0	3	5	6	6	0	3	5	6	6
	Mesial	0	0	0	6	6	M	M	M	M	M
	Distal	0	0	2	6	6	0	0	2	6	6
	Buccal	0	0	0	6	6	M	M	M	M	M
	Lingual	0	0	0	6	6	M	M	M	M	M

FIGURE 2

SCHEME FOR BASIC CARIES INCIDENCE MATRIX

		Year of Caries Onset on Left Side (Initial Diagnosis)					Sound on	
		Exam 1	Exam 2	Exam 3	Exam 4	Exam 5	Exam 5	Exam 5
Year of Caries Onset on Right Side (Initial Diagnosis)	Exam 1	X	X	X	X	X	X	
	Exam 2	X	S	1	2	3	X	
	Exam 3	X	1	S	1	2	X	
	Exam 4	X	2	1	S	1	X	
	Exam 5	X	3	2	1	S	X	
	Sound on Exam 5	X	X	X	X	X	X	

Code

- X = surface pairs for which the exact year of caries onset cannot be determined on both sides
- S = surface pairs that became carious during the same year on both sides
- 1 = surface pairs that became carious one year apart
- 2 = surface pairs that became carious two years apart
- 3 = surface pairs that became carious three years apart

TABLE 1

BASIC CARIES INCIDENCE MATRIX FOR THE OCCLUSAL SURFACE OF THE
MAXILLARY SECOND MOLAR, NON-FLUORIDE GROUP

Year of Caries Onset on Right Side (initial diagnosis)	Year of Caries Onset on Left Side (initial diagnosis)						Totals
	Exam 1	Exam 2	Exam 3	Exam 4	Exam 5	Sound on	
						Exam 5	
Exam 1	6	1	5	0	0	0	12
Exam 2	5	13	3	2	0	0	23
Exam 3	2	5	8	2	4	0	21
Exam 4	1	1	3	8	1	1	15
Exam 5	0	0	4	5	3	4	16
Sound on Exam 5	0	0	0	0	0	2	2
Totals	14	20	23	17	8	7	89

TABLE 2

NUMBER OF SURFACE PAIRS SHOWING VARIOUS TIME SPANS
BETWEEN RIGHT-LEFT CARIES ONSET,
NON-FLUORIDE GROUP

Surface	Same Year Onset	1 Year Difference	2 Year Difference	3 Year Difference	% With 1 Year Difference or More
Occlusal Mx7	32	19	11	0	48 (30/62)
Mesial Md7	6	4	3	0	54 (7/13)
Distal Mx5	5	3	2	0	50 (5/10)
Lingual Mx7	8	6	2	0	50 (8/16)
Buccal Md7	5	3	4	0	58 (7/12)

TABLE 3

CROSS SECTIONAL CARIES PREVALENCE OF THE OCCLUSAL SURFACE OF THE
MAXILLARY SECOND MOLAR, NON-FLUORIDE GROUP AT EXAMS 1, 2, 3, 4 and 5

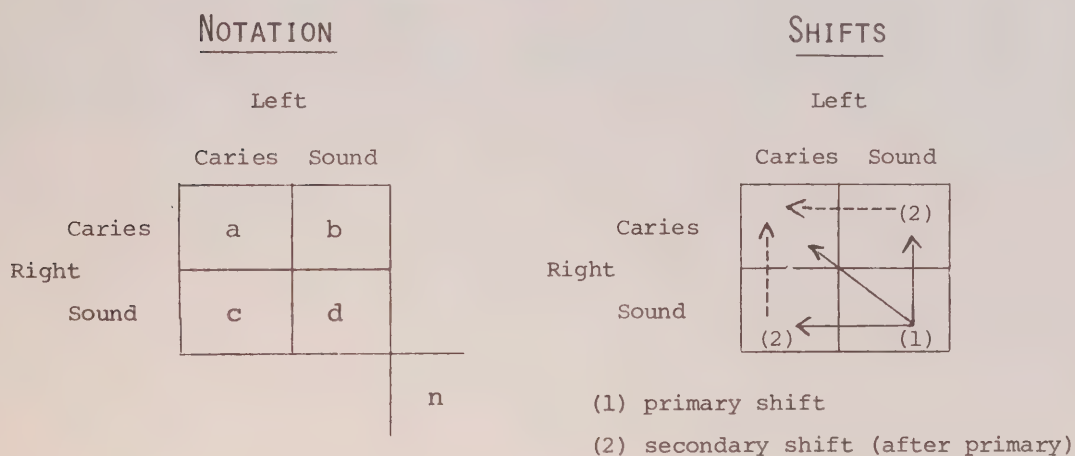
Exam 1		Exam 2		Exam 3		Exam 4		Exam 5	
Left		Left		Left		Left		Left	
Caries Sound		Caries Sound		Caries Sound		Caries Sound		Caries Sound	
Caries	6	Caries	25	Caries	48	Caries	65	Caries	82
Right	8	Right	9	Right	9	Right	9	Right	0
Sound	69	Sound	45	Sound	24	Sound	6	Sound	5
Binomial Test	p = .79	p = 1.0	p = 1.0	p = .61	p = .06				
Normal Test	p = .60	p = .82	p = .81	p = .44	p = .02				
Fisher's Exact Test	p = .0028	p < .00005	p < .00005	p = .0002	p = .0054				

TABLE 4

CARIES INCREMENTS OF THE OCCLUSAL SURFACE OF THE MAXILLARY SECOND MOLAR,
NON-FLUORIDE GROUP 1, 2, 3 AND 4 YEARS AFTER SOUND-SOUND BASELINE

After 1 Year (0-1)		After 2 Years (0-2)		After 3 Years (0-3)		After 4 Years (0-4)	
Left		Left		Left		Left	
Caries Sound		Caries Sound		Caries Sound		Caries Sound	
Caries	13	Caries	29	Caries	45	Caries	62
Right	5	Right	8	Right	9	Right	0
Sound	45	Sound	24	Sound	6	Sound	5
Binomial Test	p = 1.0	p = 1.0	p = .61	p = .61	p = .06		
Normal Test	p = .76	p = 1.0	p = .44	p = .44	p = .02		
Fisher's Exact Test	p < .00005	p < .00005	p < .00005	p = .0017	p = .0090		

FIGURE 3: DENTAL CARIES RIGHT-LEFT PAIR NOTATION
AND POSSIBLE SHIFTS TO CARIES STATE



CODE

- a = number of surface pairs carious on both sides
- b = number of surface pairs carious on right side
and sound on left side
- c = number of surface pairs carious on left side
and sound on right side
- d = number of surface pairs sound on both sides
- n = total number of surface pairs

6 pairs shifted from sound-sound to carious on the right side only.

Where sufficient data were available, each of the four incremental and five cross-sectional tables for each tooth pair was tested statistically for symmetry and association. Two methods were used to test for symmetry: a normal test, as described by Lu¹; and a binomial test⁸. These are outlined in Figure 4. The two tests of symmetry are similar in that they are both primarily concerned with cells b and c, the pairs with unilateral caries. The normal deviate is used to assess the equivalence of the two caries rates p and q; so with this test the overall sample size is considered. The binomial test simply compares the counts in cells b and c with a 50:50 split; this is analogous to the McNemar χ^2 test⁸ which is often used in fissure sealant studies.

For testing association, Fisher's exact test⁸ was used. This was chosen over the ordinary χ^2 test because some of the expected values in the of the 2 by 2 tables were less than 5.

FIGURE 4

TESTS OF SYMMETRY

Normal Test

$$Z = \frac{p - q}{S_{p-q}}$$

$$\text{where } p = \frac{a + c}{n} \quad (\text{overall caries rate on left side})$$

$$q = \frac{a + b}{n} \quad (\text{overall caries rate on right side})$$

$$\text{and } S_{p-q} = \sqrt{\frac{b + c - (b-c)^2/n}{n(n-1)}}$$

The normal deviate Z is tested against the normal probability distribution (two-tailed test). If the probability, under the hypothesis of equal caries rates, of obtaining a difference in caries rates that is greater than or equal to the observed difference is small, then there is evidence of asymmetry.

Binomial Test

$$P(X \leq m) = 2 \sum_{m=0}^x \binom{b+c}{x} \left(\frac{1}{2}\right)^{b+c},$$

where m is the minimum of b and c ;

The null hypothesis is that $b=c$, i.e. that caries are equally likely on the left and right sides.

p is the probability of obtaining a minimum value of b and c which is less than or equal to the observed minimum value, under the null hypothesis. Thus, a high probability indicates that there is symmetry, a low probability that there is lack of symmetry.

Findings

Table 1 shows the basic caries incidence matrix for the occlusal surface of the maxillary second molar for the non-fluoride group. As shown diagrammatically in Figure 2 certain cells in such a matrix are usable and others are not usable. Because the children were examined over a four-year period only, it was not possible to determine the exact year of caries onset of both sides of those surface pairs in which the left (5 + 2 + 1 + 0) or right (1 + 5 + 0 + 0) or both (6) sides were carious on the first examination, or in which the left (0 + 0 + 1 + 4) or right (0 + 0 + 0 + 0) or both (2) sides were sound on the fifth examination. Thus there was a total of 27 such "unusable" surface pairs in this table. Of the remaining 62 "usable" surface pairs, 32 (adding the numbers on the squares on the main diagonal: 13 + 8 + 8 + 3), or 51% had the same years of clinically detectable caries incidence on the left and right sides. A one-year difference in caries initiation was seen in 19 pairs (adding the circled numbers on the first minor diagonals in Table 1: 5 + 3 + 5 + 3 + 2 + 1), and a two-year difference was seen in 11 pairs (adding the numbers in the triangles: 1 + 4 + 2 + 4). Thus, 30 (or 48%) of the 62 surface pairs in which both surfaces became carious during the time of the study, did not both become carious in the same year. As shown in Table 2, this percentage ranges from 48% to 58% for the other four surface pairs examined in this fashion for purpose of demonstration. It is surprising to find that, in a simple descriptive analysis such as this, about one-half of the "usable" surface pairs became carious one or more years apart.

Pursuing the occlusal maxillary second molar (non-fluoride group) example further, it was found when examining the cross-sectional caries prevalence tables (Table 3) that strong association ($p < .01$) occurred throughout the five yearly exams. Marginally significant asymmetry ($p = .06$ binomial test; $p = .02$, normal test) is seen to occur in the last exam. The results from the four corresponding incremental tables (Table 4) are very similar.

A basic caries incidence matrix was generated for each of the 30 surface pairs (3 teeth x 2 arches x 5 surfaces) for each of the two groups. The levels of caries incidence and prevalence on 16 of these surface pairs were so low that incremental and cross-sectional tables were not derived, nor were tests of symmetry and association performed. The basic caries incidence matrix for one such surface pair is shown in Table 5 as an example of this situation. (Although these data in Table 5 did not undergo a statistical analysis, it is interesting to note that, of the thirteen pairs in which at least one surface became carious,

TABLE 5

EXAMPLE OF A BASIC CARIES INCIDENCE MATRIX FOR A
SURFACE WITH A LOW LEVEL OF CARIES INCIDENCE:
MESIAL SURFACE OF THE MANDIBULAR FIRST BICUSPID, NON-FLUORIDE GROUP

		Year of Caries Onset on Left Side (initial diagnosis)						
							Sound on Exam 5	Totals
		Exam 1	Exam 2	Exam 3	Exam 4	Exam 5		
Year of Caries Onset on Right Side (initial diagnosis)	Exam 1	0	0	0	1	0	0	1
	Exam 2	0	0	0	0	0	1	1
	Exam 3	0	0	0	0	0	1	1
	Exam 4	0	0	0	0	0	1	1
	Exam 5	0	0	0	0	0	1	1
	Sound on Exam 5	0	1	1	2	4	81	89
	Totals	0	1	1	3	4	85	94

there are no cases of both sides becoming carious within the same year, and only one case where both sides became carious during the entire four-year duration.)

One hundred and forty yearly cross-sectional tables were developed from the 28 caries incidence matrices (14 surfaces x 2 groups). Of these, five were not tested for symmetry and eleven were not tested for association, because of small numbers in the b and c cells.

Of the 135 cross-sectional tables tested for symmetry, only five showed significant asymmetry ($p < .05$) using the binomial test, and fourteen showed asymmetry using the normal test. These counts are about what one would expect from pure chance when operating at the 5% significance level.

Of the 129 cross-sectional tables tested for association, there were 35 which did not show significant association, according to Fisher's test. Table 6 shows which of the cross-sectional tables were tested for association, and which ones gave significant or non-significant results. Table 7 shows the numbers and percentages of cross-sectional tables showing non-significant association, broken down by surface, exam, arch, and group.

One hundred and twelve incremental tables were developed from the 140 cross-sectional tables (a set of 4 incremental tables from each set of 5 cross-sectional tables). Of these, one was not tested for symmetry and eight were not tested for association because of small numbers in the b and c cells.

Of the 111 incremental tables tested for symmetry, only 6 showed significant asymmetry ($p < .05$) using the binomial test, and 11 showed asymmetry using the normal test. As with the cross-sectional tables, these results are not far from what would be expected by chance, so it can be concluded that the data do show symmetry.

Of the 104 incremental tables tested for association, significant association was not found in 49. Table 8 shows which of the incremental tables were tested for association, and which ones gave significant and non-significant results. Table 9 shows the numbers and percentages of incremental tables displaying non-significant association, broken down by surface, incremental period, arch, and group.

In general, the lack of association was lower for the cross-sectional data than for the incremental data. For both the cross-sectional and incremental data, there were greater percentages of non-significant associations for interproximal (mesial and distal) surfaces than for occlusal surfaces, less association in the

TABLE 6

TESTS OF ASSOCIATION FOR CROSS-SECTIONAL SURFACE-PAIR TABLES (FISHER'S EXACT TEST)

Non-Fluoride Group

Tooth and Surface

Exam	Mx 7		Mx 5		Mx 4		Mx 7		Mx 5		Mx 4	
	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B
1	*	/ / / /	✓	* ✓ / /	*	/ ✓ / /	*	/ / / /	*	/ / / /	/	/ / / /
2	*	/ / ✓ /	*	✓ ✓ / /	*	/ * / /	*	/ / / ✓	*	✓ ✓ / /	*	/ / / /
3	*	/ / ✓ /	*	* ✓ / /	*	/ * / /	*	/ / / *	*	✓ * / /	*	/ / / /
4	*	/ / ✓ /	*	✓ * / /	*	/ * / /	*	/ / / *	*	✓ * / /	*	/ / / /
5	*	/ / * /	*	* * / /	*	/ * / /	*	/ / / *	*	✓ * / /	*	/ / / /

/ - Surface-pair table not tested for association

* - Association significant at the 5% level

✓ - Association not significant at the 5% level

15

Fluoride Group

Tooth and Surface

Exam	Mx 7		Mx 5		Mx 4		Mx 7		Mx 5		Mx 4	
	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B
1	*	/ / * /	*	/ * / /	✓	/ / / /	*	/ / / *	✓	/ * / /	*	/ / / /
2	*	/ / ✓ /	*	✓ ✓ / /	✓	/ / / /	*	/ / / *	*	✓ * / /	*	/ / / /
3	*	/ / ✓ /	*	✓ * / /	✓	/ ✓ / /	*	/ / / *	*	✓ * / /	*	/ / / /
4	*	/ / * /	*	* ✓ / /	*	/ ✓ / /	*	/ / / *	*	✓ * / /	*	/ / / /
5	✓	/ / * /	*	* ✓ / /	*	/ ✓ / /	✓	/ * / *	*	* * / /	*	/ / / /

TABLE 7

NUMBER AND PERCENT OF TABLES DISPLAYING LACK OF ASSOCIATION AT
THE 5% SIGNIFICANCE LEVEL BY SURFACE, BY EXAM, BY ARCH AND
BY GROUP -- CROSS-SECTIONAL DATA

	Number of Surface-Pair Tables Not Showing Association (p > .05)	Total Number of Surface-Pair Tables Tested	% Not Showing Association
<u>Surface</u>			
Occlusal			
Non-fluoride	1	29	3
Fluoride	6	30	20 } 12
Mesial			
Non-fluoride	6	15	40
Fluoride	5	10	50 } 44
Distal			
Non-fluoride	5	14	36
Fluoride	6	13	46 } 41
Buccal			
Non-fluoride	1	4	25
Fluoride	0	5	0 } 11
Lingual			
Non-fluoride	3	4	75
Fluoride	2	5	40 } 56
<u>Exam</u>			
1 Year			
Non-fluoride	3	10	30
Fluoride	2	10	20 } 25
2 Years			
Non-fluoride	6	14	43
Fluoride	5	12	42 } 42
3 Years			
Non-fluoride	3	14	21
Fluoride	5	13	38 } 30
4 Years			
Non-fluoride	3	14	21
Fluoride	3	14	21 } 21
5 Years			
Non-fluoride	1	14	7
Fluoride	4	14	29 } 18
<u>Arch</u>			
Maxillary			
Non-fluoride	10	34	29
Fluoride	14	32	44 } 36
Mandibular			
Non-fluoride	6	32	19
Fluoride	5	31	16 } 17
<u>Group</u>			
Non-fluoride	16	66	24
Fluoride	19	63	30 } 27

TABLE 8

TESTS OF ASSOCIATION FOR INCREMENTAL SURFACE-PAIR TABLES (FISHER'S EXACT TEST)

Non-Fluoride GroupTooth and Surface

Incremental Period	M _x 7		M _x 5		M _x 4		M _d 7		M _d 5		M _d 4	
	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B
1 Year	*	/ / Q /	Q	Q Q / /	*	/ / / /	*	Q / / Q	Q	Q Q / /	*	/ / / /
2 Years	*	/ / Q /	*	Q / / /	*	/ / / /	*	/ / / Q	*	Q * / /	*	/ / / /
3 Years	*	/ / * /	*	Q * / /	*	/ Q / /	*	/ / / *	*	Q * / /	*	/ / / /
4 Years	*	/ / * /	*	Q Q / /	*	/ Q / /	*	/ / / *	*	Q * / /	*	/ / / /

/ - Surface-pair table not tested for association

* - Association significant at the 5% level

Q - Association not significant at the 5% level

Fluoride GroupTooth and Surface

Incremental Period	M _x 7		M _x 5		M _x 4		M _d 7		M _d 5		M _d 4	
	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B	O	M D L B
1 Year	*	/ / Q /	*	Q / / /	Q	/ / / /	Q	/ / / Q	Q	Q / / /	/	/ / / /
2 Years	*	/ / * /	Q	Q Q / /	Q	/ Q / /	*	/ / / Q	*	Q Q / /	Q	/ / / /
3 Years	*	/ / Q /	Q	* Q / /	Q	/ Q / *	*	/ / / *	*	Q * / /	Q	/ / / /
4 Years	Q	/ / * /	Q	* Q / /	*	/ Q / /	Q	* / / *	*	Q * / /	*	/ / / /

TABLE 9

NUMBER AND PERCENT OF TABLES DISPLAYING LACK OF ASSOCIATION
AT THE 5% SIGNIFICANCE LEVEL BY SURFACE, BY INCREMENTAL PERIOD, BY ARCH
AND BY GROUP -- INCREMENTAL DATA

	Number of Surface-Pair Tables Not Showing Association (p > .05)	Total Number of Surface-Pair Tables Tested	% Not Showing Association
<u>Surface</u>			
Occlusal			
Non-fluoride	2	24	8
Fluoride	12	23	52
			} 30
Mesial			
Non-fluoride	8	12	67
Fluoride	6	10	60
			} 64
Distal			
Non-fluoride	6	10	60
Fluoride	7	9	78
			} 68
Buccal			
Non-fluoride	2	4	50
Fluoride	2	4	50
			} 50
Lingual			
Non-fluoride	2	4	50
Fluoride	2	4	50
			} 50
<u>Incremental Period</u>			
1 Year			
Non-fluoride	9	13	69
Fluoride	7	9	78
			} 73
2 Years			
Non-fluoride	4	13	31
Fluoride	9	13	69
			} 50
3 Years			
Non-fluoride	3	14	21
Fluoride	7	14	50
			} 36
4 Years			
Non-fluoride	4	14	29
Fluoride	6	14	43
			} 36
<u>Arch</u>			
Maxillary			
Non-fluoride	11	26	42
Fluoride	17	26	65
			} 54
Mandibular			
Non-fluoride	9	28	32
Fluoride	12	24	50
			} 41
<u>Group</u>			
Non-fluoride	20	54	37
Fluoride	29	50	58
			} 47

maxillary arch than in the mandibular arch, and less association in the fluoride than the non-fluoride groups. In particular, the occlusal surfaces in the non-fluoride groups had relatively few non-significant associations; this accounts for a large part of the overall group and surface differences.

Discussion

The findings that, over all five years, about one-half of the tooth surfaces so evaluated were not diagnosed as becoming carious in the same year prompted further detailed study into the bilaterality of dental caries prevalence and incidence. Before discussing the implications of these more detailed findings, and especially the incidence ones, four possible explanations for the apparent deviations from bilaterality should be explored. The four explanations are that the deviations from bilaterality are due to: (1) the initial data adjustments preceding this analysis; (2) a systematic right-left clinical examiner bias; (3) the insensitivity of annual exams to slight time differences in right-left caries onset; and (4) a real (biological) difference in the occurrence of decay between right and left surfaces. Obviously, combinations of these factors are also possible. (A fifth possibility, that the data used here are very aberrant regarding bilaterality, cannot be dismissed, nor can this be proven or disproven until many other replicative studies are performed.) Discussion of each of the four possible explanations follows.

Initial data adjustments were necessary to correct the inconsistencies and obvious errors that occur in any longitudinal caries clinical trial, and especially one that includes a dental caries scoring category for recording questionable enamel lesions as opposed to only definite lesions. This cleaning of the data involved relatively few surfaces (about 5% of the total) and was not biased towards creating or discouraging simultaneity of caries attack.

The frequency of significant asymmetries as revealed by the binomial test is consistent with the number of expected asymmetries based on chance alone when many such significance tests are performed at the 5% significance level. Since the binomial test essentially compares unilateral right and left caries (in cells b and c) against a probability of 0.5, it is very unlikely that a right or left systematic bias of the original clinical examiners existed.

It is possible that the onset of clinically observable dental caries on right and left surfaces differs by only a matter of months. An annual examination taking place during this brief onset interval might then not be a sensitive indication of bilaterality. It is unlikely, however, that such an explanation would account for the deviations in the onset of caries of one year or more in 50% of surface pairs as observed here; and certainly this would not explain the deviations of two years observed in about 19% of the surface pairs so examined.

Relative to the fourth explanation, it is possible that there is a real, biological basis for deviation from bilaterality, not only in terms of the symmetry of this attack, but especially in terms of the (positive) association of the incidence of caries attack between the two sides. It must be stressed that the deviations from bilaterality observed here do not always occur, but they do appear to occur with greater frequency than chance alone would determine, and is generally assumed.

Although lack of (positive) association of dental caries attack between the two sides was observed in the prevalence data of the five cross-sectional examination years, the bilaterality of caries incidence is of more interest because its occurrence is an implicit assumption of the split-mouth clinical trial experimental design.

Several questions arise regarding the bilaterality of caries incidence:

1. What aspect of incidence bilaterality (symmetry or positive association or both) is the most important consideration?
2. Are the statistical tests available to assess the most important aspect(s) identified above appropriate for, and sensitive to practical clinical applications?
3. Should the standard statistical testing procedures applicable to the split-mouth design analysis be adjusted to account for greater than chance deviations in dental caries incidence bilaterality or are new statistical tests required?

Regarding question 1, it seems that both symmetry and high positive association should be important. However, when there is high positive association, the number of unilateral caries is generally relatively small; thus, whether or not the b and c cell counts are approximately equal, i.e., whether or not symmetry is present, is of little consequence.

Regarding question 2, the appropriate statistical test would be χ^2 , corrected for continuity as required, or Fisher's exact test for 2 x 2 tables, which is applicable to all sample size situations but especially necessary with small expected frequencies. The observation that 49 of the 104 incidence table surface pairs did not show significant association would give cause for concern and point out the need for a closer look at the unilateral-bilateral surface

pair situation represented by these 49 tables. It cannot be assumed, however, that all remaining tables showing the anticipated positive, statistically significant association display marked bilaterality in a practical, clinical sense. For example, Table 4 traced what happened to 69 initially sound-sound maxillary second molar occlusal surface pairs at the baseline examination and after one, two, three and four years. According to Fisher's exact test of association there was highly significant (positive) association of the caries attack rate on each side in each of the four examination intervals. Despite this association, the numbers of unilateral carious surface pairs relative to the total unilateral plus bilateral carious surface pairs as tabled below are very high for the first three examination intervals (46%, 36%, 25%).

Interval (Yrs.)	No. of Unilateral Carious Pairs	No. of Bilateral Carious Pairs	% of Surface Pairs with Caries that are Unilateral
0 -1	11	13	45.8%
0 -2	16	29	35.6%
0 -3	15	45	25.0%
0 -4	5	62	8.1%

Thus, significant associations arising from the most appropriate statistical test mask what may be important clinical differences in the bilaterality of dental caries incidence.

Concerning question 3, the usual tests of significance in the analysis of fissure sealant^{2,3,4,5} and flossing⁶ studies are the binomial test^{5,6} and McNemar's χ^2 ^{2,3,4}. These two tests are essentially equivalent. Both tests inherently assume that when the null hypothesis is rejected, observed differences in dental caries incidence (assuming they are in the right direction) between the treatment and control sides are due to the experimental intervention (flossing or sealing). Now it appears from this study that another component of variability, that is, lack of simultaneous decay, is superimposed on that due to chance difference between sides. This superimposition, it is stressed, appears to apply to some surfaces and some examination intervals more than others. If a real, biological tendency for unilaterality of caries incidence exists it seems that some adjustment to present statistical analysis methods or new methods would be required. Otherwise, for those sites or situations in which bilaterality

is less likely, experimenters may make claims about an agent or procedure based on the split-mouth experimental design that overstates or understates the effect of the intervention. Also, further investigations are required to determine whether significant unilaterality favours equally the right and left sides, and under random assignment of treatments to one side, actually has a cancelling-out or biasing effect. This effect may be agent- or procedure-dependent. For example, with flossing, the net effect on the flossed and unflossed side may cancel out, whereas with a retained fissure sealant, unilaterality may bias the interpretation.

Although it was the purpose of this report to analyze and report upon the presence and extent of bilaterality in dental caries prevalence and especially incidence, some conclusions and guidelines in view of the unexpected findings are offered:

1. Although dental caries surface prevalence and incidence display bilaterality, i.e. significant symmetry and association, surprisingly large deviations from bilaterality or unilaterality also occur, especially with incidence data.
2. While generalizations are dangerous in view of the preliminary nature of the present analysis, the small sample size, and the need for replications of this study by others, it appears that the interproximal mesial and distal surfaces display less bilaterality (more lack of statistical association) and that bilaterality increases as length of the interval between the baseline and subsequent examination increases.
3. Statements about the surface sites where bilaterality is less evident are complicated by the finding that even when the expected positive statistical association exists, rather large percentages of the total pairs of surfaces with decay are unilateral.
4. Replication of this study by others with larger samples is very important and can be relatively easily accomplished with existing clinical trial data. However, as shown in this report, it is desirable to have longitudinal data covering at least four years since much data are lost in the initial and final years because of uncertainty about the actual time of the onset of unilateral decay in these years.

5. Detailed studies of the implications of significant unilaterality for statistical analysis and of the sites and other characteristics of unilaterality are needed. The hypothesis that surfaces less susceptible to decay are more liable to decay unilaterally and vice versa needs testing.
6. Lu¹ suggested that lack of bilaterality was a developmental phenomenon and that symmetry and association would tend to occur simultaneously as time progressed. The results of this investigation seem to support Lu's hypothesis for association but not for symmetry.

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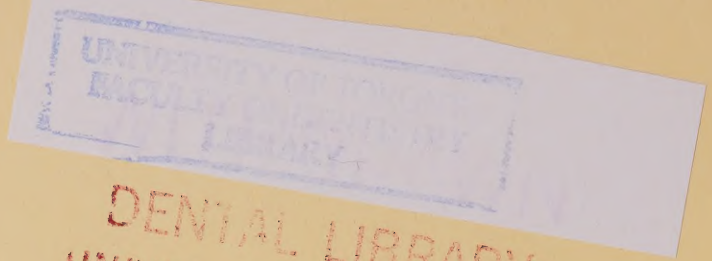
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APPENDIX 1

EXAMPLES OF SYMMETRY AND ASSOCIATION

A - No Symmetry No Association		B - No Symmetry Association		C - No Symmetry Negative Association	
Left		Left		Left	
Caries	Sound	Caries	Sound	Caries	Sound
Right Caries	20	Right Caries	30	Right Caries	5
Sound	50	Sound	40	Sound	65
	70		70		70
	30		30		30
	100		100		100

D - Symmetry No Association		E - Symmetry Association		F - Symmetry Negative Association	
Left		Left		Left	
Caries	Sound	Caries	Sound	Caries	Sound
Right Caries	50	Right Caries	65	Right Caries	40
Sound	20	Sound	5	Sound	30
	70		25		0
	30		30		30
	100		100		100



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